

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General



SCHERING PLOUGH, INC.

PRESS RELEASE on CLARITIN BEST PRICE SETTLEMENT

The National Association of Medicaid Fraud Control Units (“NAMFCU”) and the District of Columbia Office of the Inspector General, Medicaid Fraud Control Unit announced in July 2004, that they had reached an agreement in principle with pharmaceutical manufacturer Schering Plough, (“Schering”) to pay \$140.7 million to the State Medicaid Programs for damages and penalties from Schering’s underpayment of Medicaid Drug Rebates on its blockbuster antihistamine drug, Claritin. As part of the settlement, the District of Columbia has recovered \$ 766,713.87 in restitution and penalties. The agreement in principle involves 49 states plus the District of Columbia.

The Federal Medicaid Drug Rebate statute requires that all pharmaceutical manufacturers which supply products to Medicaid recipients provide the Medicaid Programs the benefit of the “best price” available for that product. The manufacturers are obligated to file “best price” information with the Centers for Medicare and Medicaid Services (“CMS”); CMS then uses this information to calculate rebates for the state Medicaid Programs. The federal law requires the “best price” reported by manufacturers be inclusive of discounts, rebates, payments and other incentives. In this case it was alleged that Schering, when negotiating with two HMOs to keep Claritin on formulary in lieu of a competitor product, provided the HMOs with certain discounts, concessions and incentives, which were then not reported to CMS as part of the Claritin “best price.” The result was that the states received millions less in rebates from Schering than would have been paid had “best price” reporting been done appropriately.

The alleged conduct impacting best price included Schering’s payment of a \$2.5 million “data processing fee” to one of the HMOs for utilization reports the HMO was otherwise already obligated to provide Schering; Schering’s “prepayment of rebates,” the equivalent of providing interest free loans; and Schering’s agreement to pay one HMO’s antihistamine costs if those costs reached a certain percentage over the prior year.

The states’ settlement was reached in conjunction with a federal settlement negotiated by the United States Attorney’s Office in Philadelphia, PA. Under the federal agreement, Schering Sales Corporation, a subsidiary of Schering, will plead guilty to federal criminal anti-kickback charges, and pay a fine of \$52.5 million. Schering also entered into a civil false claims settlement in federal court in Philadelphia. Schering will pay a total of \$282.3 million to resolve its civil liability for underpaying Medicaid drug rebates. The United States Government will collect the federal portion of the recovery, and the states’ \$140.7 million share is allocated according to states’ respective Medicaid Program utilization for Claritin. The state settlement team was led by the Directors of the Ohio, Oregon, and Pennsylvania Medicaid Fraud Control Units and a Senior Assistant Attorney General from the Illinois MFCU. The monetary recovery for the states from the settlement represents double the actual damages sustained from the underpayment of rebates.

As part of the agreement in principle with the states, Schering will be required to report accurate pricing information to the federal and state governments on many of its products. Schering also entered into a Corporate Integrity Agreement (“CIA”) with the United States Department of Health and Human Service’s Inspector General, which will require strict scrutiny of Schering’s pricing and sales practices for the next five years.

For further information, please contact Barbara Zelner, counsel for NAMFCU, (202) 326-6020, or Susan Bieber Kennedy, Director of the District of Columbia Medicaid Fraud Control Unit (202) 727-2245.